



**MAITHILI LIFE SCIENCES
WELCOMES**

- 2009 - Establishment of the company
- MLS is a private limited company ,a part of Maithili group of companies based in India (MAM,MAC, MAT,SGG) and Singapore(MITCO). The companies have a combined turnover of 50 Million USD.
- Started off as a CRO (Custom research Organization) in Hyderabad and later on expanded for manufacturing API's.
- GMP certification by Kurnool FDA 2015

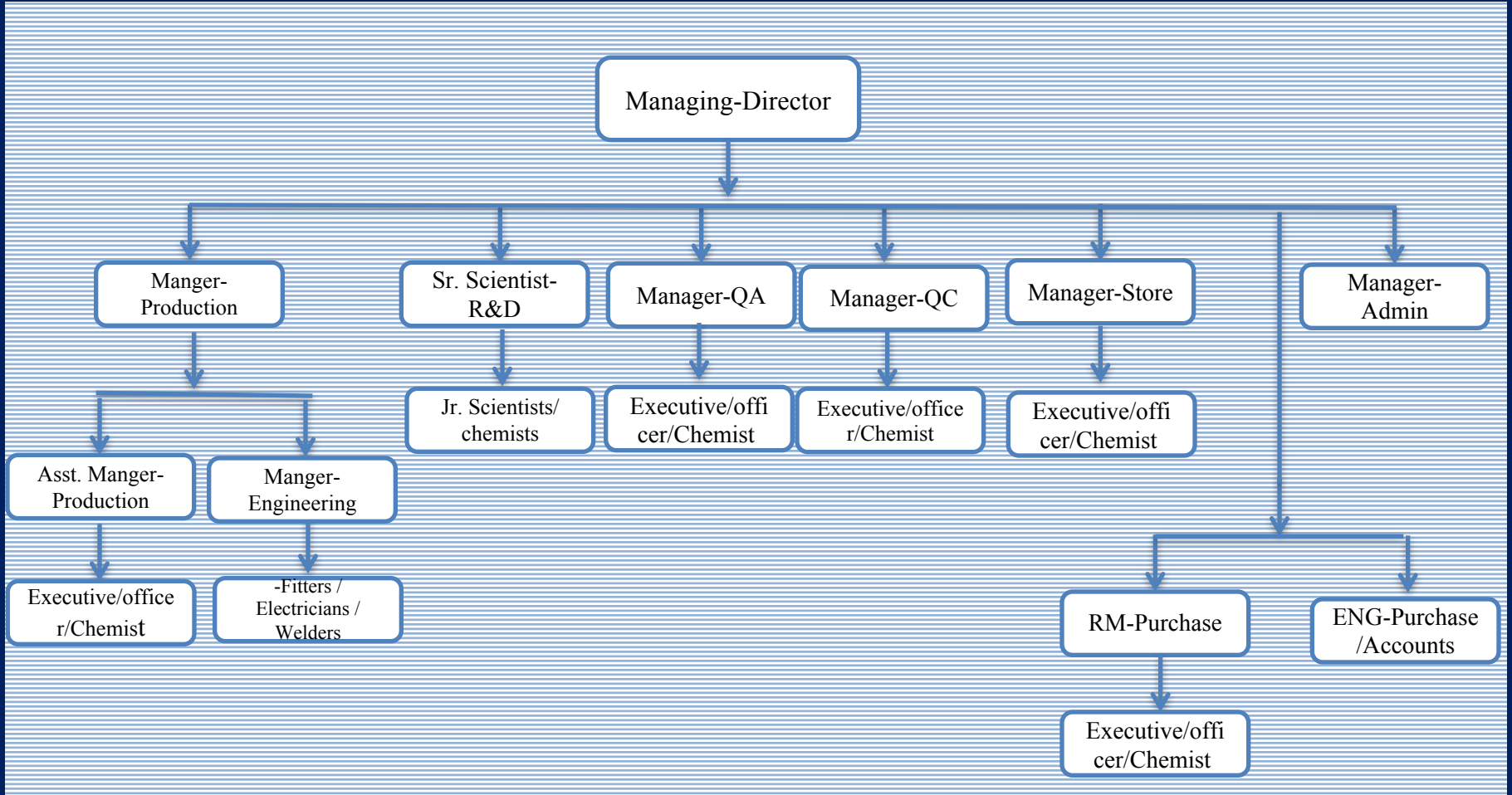
**Developing and manufacturing
challenging Active Pharmaceutical Ingredients
of high quality and fine chemicals.**

**To be a Partner of Global Health Care Industry For Supplying
High Quality Pharmaceutical Products At Competitive Prices
Complying With Stringent Regulatory Requirements**

- **Well established R&D center**
- **Manufacturing unit is Indian FDA approved.**

Mr. Gopinath Reddy , Managing Director

He has completed his Masters from USA



Process Development

Chiral chemistry - Chiral resolution, Racemization

Heterocyclic synthesis

Asymmetric oxidation and reduction

Hydrogenation, Nitration and Cyanation reactions

**Reactions involved LDA, n-BuLi, NaH, Borane in THF,
(Borane in Dimethyl Sulfide) BDMS, DIBAL-H(Diisobutyl
Aluminium Hydride), Vitride, etc...**

**Non Infringing Process, Cost Reduction , Selective Polymorph,
column separations**

**Equipped with: 18 fume hoods and 2 walk-in hoods with various size,
Glass assemblies, Laboratory Hydrogenator, Rotary evaporators**

Method Validation

Method Transfer

Pharmacopeial compliance

Stability Studies

Characterization of API and Impurities

Equipped with:

HPLCs with PDA/LC detectors, Gas Chromatography with head space

Infrared Spectrophotometer, Stability Chambers

pH meters, Melting point apparatus

UV – Visible spectrophotometer, TDS/conductivity meter

KF Titrator



The QA systems are based on ICH & ISO compliant and independent from production

Vendor Qualification

In-process monitoring

Change Control Procedure

Annual Product Review

Self Inspections

Deviation Control Procedure

Complaint Handling

Product Recall and Returns

Document Control

Review of Batch Record before Release

Training and Development

Handling Out of Specifications

Water/HVAC system monitoring

Stability Study Program as per ICH

Process and Method Validations

Regulatory: DMF filing, Product registration, Accreditations

Biperiden Hydrochloride EP/USP

Dapoxetine Hydrochloride-(In-House)

Nebivolol Hydrochloride-(In-House)

Sodium amino salicylate-Not validated

Pragabalin-Not validated

Olmesartan medoxomil EP/USP

Ornidazole (In-House)

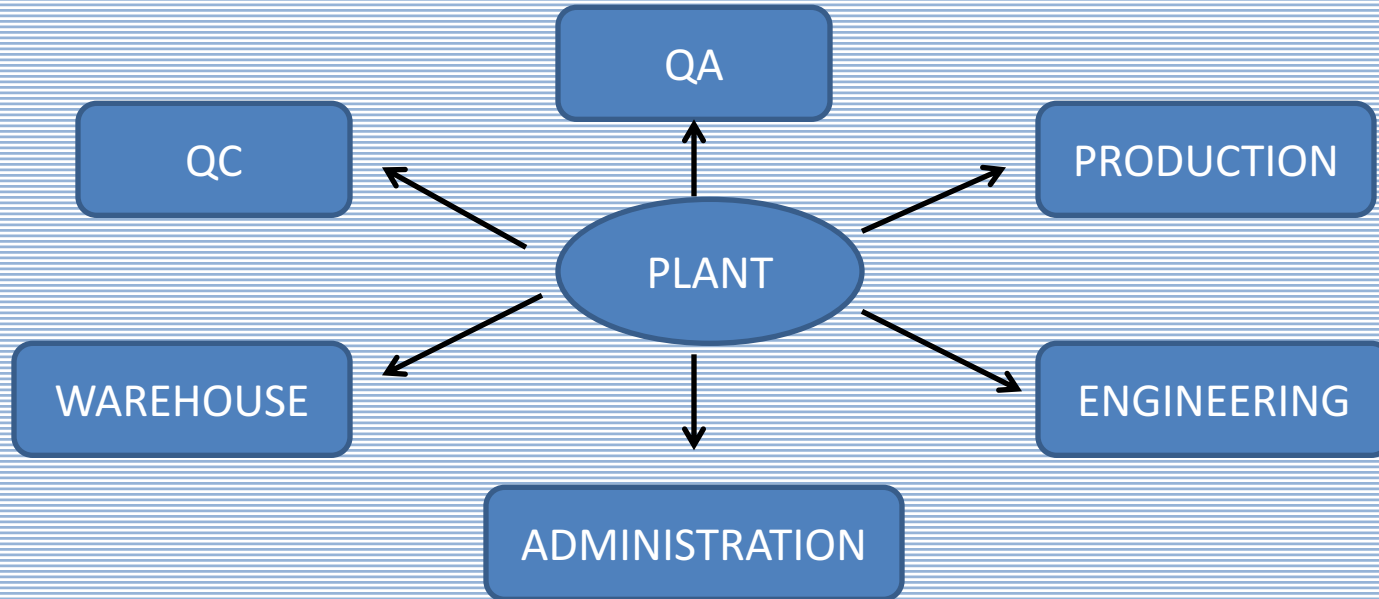
Sodium amino salicylate dyhydrate-Not validated

Dorzolamide hydrochloride-Not validated

Escitalopram oxalate-Not Validated

Product	USDMF	Applicants Part
Biperiden Hydrochloride EP/USP	U/P	
Dapoxetine Hydrochloride	U/P	

State-of-the-art- manufacturing facility at Tirupathi ; 4,35,000 sq. ft.;
a team of 50 people with an investment of USD 4.0 millions.



Three stand alone GMP suites for large volume and small volume APIs & Intermediates

Manufacturing volumes ranging from 250 L to 4000 L

14 SSRs, 7 GLR, 4 Glass assemblies, 5 centrifuges

3 TDs, 2VTDs, 2 RCVDs, 3 Shifters, 3 Millers,

2 Blenders, 4 Filters, 1 Hydrogenator

1 Dispensing Booth

TOTAL CAPACITIES

Reactor (Pilot plant)	: 3850 L
Reactor (Module-I)	: 36000 L
Reactor (Module-II)	: 1000 L
RCVD	: 700 L
Tray Drier	: 132 Trays
VTD	: 60 Trays
Blender	: 1100 L
MM	: 750 kg/hr
Sifter	: 500 kg/hr
Filters (approximately)	: 120 L

2 HPLC | GC, | 1 UV Spectrophotometer | 1 Ph Meter

MP Apparatus | 1 Ovens | 1 IR apparatus

1 UV Cabinet | 1 Vacuum oven | 1 Refrigerators

3 Stability Chambers | 1 K.F Titrate

1 TDS/Conductivity meter | 1 Muffle furnace

1 Weighing Balance

HVAC & Clean Room Environment: 12 AHUs

Purified water system

Compressed Air

Nitrogen air

Hot water Boiler

Chilled Brine plant

Diesel Generators

Scrubbers

ETP plant



















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THANK YOU